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HEPATITIS C: THE CURRENT POSITION

I attach a submission to Ministers about hepatitis C, its likely impact on the NHS and how we are proposing to deal with it. This is the outcome of discussions held within both the Executive and the wider Department since there are a number of different interests involved. The approach has also been agreed by the Executive Board. This is consistent with the work in hand on the introduction of new drugs to the NHS and colleagues handling that work have been closely involved in writing this submission.

I also attach a copy of slides[1] presented to us recently by Schering-Plough, one of the 3 drug companies involved in the production of Alpha Interferon, which PS(H) may find helpful.

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HEPATITIS C (HCV): THE CURRENT POSITION

SUMMARY.

1. There is an unknown but potentially large number of people infected with Hepatitis C (HCV), a transmissible blood borne virus with some similarities to HIV and Hepatitis B. The infection may lead to the development of severe liver disease or even liver cancer but often only after an interval of 20 years or more. There are strong public health reasons for encouraging people to come forward for testing but the treatment available is expensive and of limited effectiveness. If large numbers of people come forward for treatment it will impose significant demands on the NHS. **This submission informs Ministers of the issues raised by hepatitis C and proposes a framework for handling the disease with options for taking this forward.**

2. The NHS is faced with dealing with an unknown but potentially large number of people infected with Hepatitis C (HCV), a blood borne virus which results in persistent infection in about 80% of those exposed. It is transmitted primarily via percutaneous exposure to blood, most commonly through the sharing of contaminated equipment by injecting drug misusers. Perinatal and sexual transmission also occur but these modes of transmission appear less efficient than they are for HIV or hepatitis B. Persistent HCV infection can cause chronic hepatitis which may progress, in some, to cirrhosis and liver failure or liver cancer, although frequently not until 20 years or more after infection.

3. There are two main groups of patients. Some, like haemophiliacs and recipients of blood transfusions (minimum of 7000 cases), have been **iatrogenically infected** as a result of NHS treatment. It is not yet clear whether the Department will have to respond to writs issued from those who contracted HCV iatrogenically. The other main group is **injecting drug misusers,** both past and current, who have shared equipment. This second group, unlike the first, will keep growing unless steps are taken to prevent transmission. Transmission sexually and from mother to child is generally thought to be low but can occur so partners and children are at some risk of infection. Although estimates vary, prevalence is estimated to be between 0.1 and 1% of the population - the **best current estimate is between 150,000 and 300,000 people.** By way of comparison, in the US roughly 1.2% of the population are infected. The prevalence in some ethnic groups is said to be much higher.

4. There have been many sources of pressure on the Department to deal with hepatitis C and these are summarised in Annex A.

Objectives.

5. The objectives for the Department and the NHS in handling hepatitis C can be summarised as follows:

- as with other transmissible diseases, to handle the public health aspects of hepatitis C (see Section I below)

- to maintain public confidence; there has been criticism of the Department's stance on hepatitis C and unfavourable comparisons made with our handling of other related public health problems such as AIDS (see Section II below).

- to set a framework which will enable the NHS to manage the disease locally (action needed includes both prevention and treatment) (see Section III below).

I. Public health.

6. **Hepatitis C has important public health implications. There is a strong case and mounting pressure for sending out clear public health information to encourage people at risk to come forward for testing to:**

- limit spread
- enable people to seek advice and, where appropriate, treatment and
- reduce the long term demands on the NHS by early intervention.

Not to act to inform those at risk in the light of the knowledge available would invite continued criticism for holding back up-to-date public health advice and might prove difficult to defend. However, we have resisted too proactive a public health stance eg: the sort of publicity campaign mounted for HIV/AIDS, because of the resource implications for the NHS.

7. **The Executive Board** has considered the pressures arising from HCV and confirmed **the Department's responsibility for issuing clear public health advice despite the implications for NHS expenditure.** Suitable opportunities are now being taken, therefore, to update the public health information available so as to highlight the risks of transmitting HCV through sharing needles and other equipment, and to publicise the availability of testing for HCV. Guidance issued on purchasing drug treatment services based on the Drug Misuse Task Force Report included a section on the prevalence of HCV amongst current and ex-drug misusers and the need to make testing available.

8. Encouraging people to come forward for counselling, testing and, if appropriate, for treatment now, should not only reduce the risk of further spread but may also decrease the longer term NHS treatment costs (although the evidence on this is weak). However, such increases in advice will lead to concomitant increases in the demand for NHS services in the short term.

II. Public confidence.

9. There is a perception which has some substance that the Department is trying to keep its response to the relatively new problem of hepatitis C low key, mainly because of the resource implications of raising public awareness. We are under pressure from the drugs misuse agencies, voluntary organisations, professionals and the drug companies to take a more proactive approach to both the detection and clinical management of HCV. Media coverage is also increasing as more infected patients come to light through a number of routes, some of whom may have been infected 20-30 years ago but who are only now coming forward (see Annex A, para. j). There are many people who do not know they are infected who will only do so if advised specifically that they may be at risk. Some Health Authorities are unwilling to encourage them to come forward for testing since this will increase the demand for treatment. The Department and the NHS need to demonstrate that public health is given the highest priority in order to maintain public confidence in our handling of the illness and the NHS' ability to deal with it.

III. Implications for the NHS.

10. Inevitably, the greater the publicity given to hepatitis C, the more patients will come forward for testing and treatment. Advice can be given on modification of lifestyle to limit the risk both of transmission and of liver damage. Apart from this, the only licensed treatment currently available for the treatment of chronic hepatitis C is Alpha Interferon (licensed for this purpose in January 1995). Some 20-25% of patients with chronic hepatitis C and with evidence of moderate or severe active hepatitis treated with Alpha Interferon show a sustained response after cessation of treatment.

11. Despite the fact that the treatment has a relatively low success rate and significant side effects, specialists feel that there is sufficient evidence of clinical effectiveness to justify prescribing it for patients who may benefit. The availability of treatment, however imperfect, has increased interest in the disease and provided a stronger incentive for identifying those infected[1] than simply preventing transmission. The licensing of Alpha Interferon was the main reason why the "Lookback"

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[1] There are some similar considerations to those raised by the more recent licensing of Beta-Interferon for Multiple Sclerosis, eg: treatment is costly but not effective in many cases, the side effects may be as troublesome, and there is pressure from the voluntary sector to encourage those who may benefit to come forward for treatment.

exercise was set up to identify patients infected through blood transfusions in the course of NHS treatment (see Annex A, paragraph d).

12. In addition, the "Lookback" raised expectations that testing and treatment would be available for those infected through such NHS treatment. Specific commitments have been given about the provision of treatment in respect of haemophiliacs (whose request for compensation has recently been rejected by Ministers). Such commitments are difficult to reconcile with the fact that some patients coming forward for treatment who were infected through other routes, are being denied treatment, mainly on cost grounds. To deny any individual patient, however infected, a trial of a drug that may delay or prevent the development of serious liver damage is contentious. Conversely, to encourage people to seek treatment at a time when they are asymptomatic, and may remain so for decades, during which time more effective treatments may be developed, is equally questionable, particularly as such trials of newer treatment regimens are already in progress and are expected to report in the next few years.

13. Purchasers in some areas have made it clear that they are not willing to pay for treatment with Alpha Interferon: clinicians have been told that purchsers will not pay for treatment not covered by existing contracts. In other areas, patients with the same (or less severe) clinical condition may be offered treatment without restriction. Our policy on the availability of treatment is that Health Authorities should not rule out the purchasing of an intervention known to be clinically effective where appropriate. However, it is, in the first instance, a clinical decision as to whether it should be made available for any particular patient.

14. Raising awareness therefore poses difficulties for the NHS. The **identification of asymptomatic patients** by testing, though consistent with policy on HIV, will place increasing pressure on specialist services which are already fully-stretched. For hepatologists, HCV represents up to 2/3 of their current workload. If prevalence is in line with current estimates, the demand for counselling, testing and, where appropriate treating, HCV patients could only be met by significant increases in medical and nursing manpower. The true scale of the potential demand has yet to be assessed.

15. An estimate of the projected increase in the cost of **treatment with Alpha Interferon** is given in Annex B although much depends on how proactive we are in raising awareness (the treatment cost up to £2-5000 per patient). There is evidence of increased expenditure on Alpha Interferon in the primary care and the hospital sector - approximately 30% of the prescribing is in the preimary care sector. However, in some areas, most of the prescribing is undertaken in primary care under shared care arrangements following initiation of treatment by a hepatologist. Unlike with Beta Interferon which was a newly-licensed drug when guidance was issued to the NHS, there has been no attempt centrally to advise the NHS about prescribing.

Handling.

16. The following paragraphs describe the action that has been taken so far and summarise the options open to Ministers in handling hepatitis C:

Public Health.

17. We have allocated resources (£1m) for research into hepatitis C primarily to clarify its prevalence and natural history and the routes of transmission. We will evaluate policies in the light of any new research findings that become available;

18. Further options are:

- to launch a public health campaign and encourage screening for high risk groups

- to continue as at present to update public health advice opportunistically pointing out the risks of HCV, the behaviour likely to transmit the disease and advise those health professionals working with high risk groups to encourage people at risk to come forward for counselling and testing.

We would recommend the latter course since we do not wish to cause unnecessary concern or a surge in referrals which the NHS could not deal with, particularly given the currently limited options for treatment.

Public confidence.

19. We wish to ensure that there is public confidence both in our handling of hepatitis C and the NHS' ability to deal with it. With this in mind, we have held discussions with the voluntary organisations, one of the drug companies involved and the professionals to hear their concerns and to talk about what action the Department/Executive is taking. We have also reflected the need for increased support for patients affected in approving Section 64 grants related to hepatitis C.

20. Other pressures arise, for example, from agencies such as the Advisory Council on the Misuse of Drugs, who are pressing us to encourage people to come forward for testing. Such groups draw strong parallels between HIV/AIDS and HCV ie: they are similar viruses that may cause no symptoms for a period but will eventually lead to serious disease or death for many of those infected. They compare, unfavourably, the Department's high level response to HIV/AIDS with the, so far, minimal apparent action on HCV.

Options are:

- we resist calls to raise the profile of the disease generally and in public health/health education material specifically and try to dampen down anxiety about the likely prevalence and spread of the disease;

- we make it clear that we are taking a more proactive stance in relation to hepatitis C and that we are attempting to raise its profile responsibly and ensure that the NHS is prepared but without causing widespread alarm.

We would recommend the latter option since the guidelines that have already been issued in relation to drugs misuse make it clear that testing should be made available and we have already given commitments on treatment for some patients. In addition, we would not wish to limit public knowledge of what is a transmissible disease.

Implications for the NHS.

21. Research into the effectiveness of treatment with Alpha Interferon and drugs under development is currently being commissioned as part of the Health Technology Assessment programme. The profession are concerned that the results of this will not be available for some time and that, compared to research into HIV, research into HCV is inadequate (see Annex A, para. 8). We are discussing how this research can be progressed more rapidly.

22. In addition, we are supporting the profession in their plans to produce clinical guidelines on Alpha Interferon. This will be similar to the clinical advice issued by SMAC to help the NHS manage the introduction of Beta Interferon 1b for Multiple Sclerosis. A professional consensus conference was held in October involving organisations with an interest in HCV where the general principles on which guidelines could be based were agreed. If these are commended by COG they would be promulgated to the NHS. This initiative will be given financial support by the NHS Executive if appropriate.

23. Issuing any guidance to the NHS, even commending clinical guidance, gives an implicit signal to purchasers about the priority to be attached to a particular condition or treatment. Purchasers have indicated that guidance which could be interpreted as prescriptive would not be welcome but factual information would be helpful to purchasers and professionals working in the field. Any guidance which is produced will not require Health Authorities to test all those at risk nor to treat all those found to be HCV positive, but should ensure that HAs do not put a blanket ban on the testing and treatment of HCV patients.

24. The options for handling are:

- issuing guidance to purchasers in addition to the clinical guidelines on treatment which the profession seem likely to develop; purchasing guidelines could address aspects of the disease other than treatment such as the need for counselling and clarifying policy on testing;

- that we do not issue purchasing guidance but advise that the management of patients with HCV is a matter for clinical judgement as are decisions about which patients might benefit from treatment. There should be no blanket bans on treatment but overall resource allocation to HCV must be a matter for local decision.

We would recommend the latter since issuing purchasing guidance in addition to factual clinical guidelines on treatment could be interpreted as giving a signal about priorities which purchasers are unlikely to find helpful. In parallel to this, we may raise the cost of testing and treatment as a new pressure in PES97.

25. Ministers views are sought on the options outlined above for handling hepatitis C.

ANNEX A

Pressures to respond to the problem of Hepatitis C:

The following gives details of the main pressures that we are currently facing to address the problems raised by hepatitis C:

Advisory Council on the Misuse of Drugs (ACMD):

a. The ACMD has expressed concern about the potential increase of HCV among drug misusers unless clear advice is given about the dangers of HCV and the need for testing. They are equally concerned about the potentially large numbers of ex-drug misusers who may be unaware that they are infected. **The "Clinical Guidelines on Drug Misuse and Dependence" issued to all doctors in 1991 advises testing for HCV and follow-up.** Guidance was also issued to Health Authorities last year on drug misuse services which referred to the high prevalence of hepatitis C amongst injecting drug users and former injectors. This asked Health Authorities to review prevention programmes. **With such guidance already issued, it is difficult to counteract pressure from the ACMD for a comprehensive response including measures to prevent spread and provide access to treatment and counselling for those who may benefit.**

Task Force on Effectiveness of Drugs Services.

b. The report of the Task Force set up to review the effectiveness of drugs services was published on 1 May. It draws attention to the large numbers of drug misusers infected with Hepatitis C and consequent treatment implications. It recommends that the Department should consider how people who could benefit from treatment should be encouraged to come forward. **More generally, the White Paper, "Tackling Drugs Together" explicitly commits Government, and at local level multi-agency Drug Action Teams, to develop accessible services and to reduce the health risks and other damage associated with drug misuse.**

Voluntary sector.

c. The voluntary organisations (eg: the British Liver Trust (BLT) and the Haemophilia Society), supported by the profession, are lobbying the Department for additional resources for this group of patients and for publicising how HCV can be prevented and treated. The BLT, in particular, feel that they need more central funding to enable them to respond to the growing demand for information from patients.

"Lookback" into infected blood.

d. The "Lookback" of blood transfusion recipients infected with hepatitis C prior to the introduction of screening blood for Hepatitis C in September 1991 has created further pressure. It is likely that approximately 3000 recipients of infected blood who are still alive a re likely to be identified by this exercise, and they are currently being traced. Ministers have given assurances that these patients will be tested and, if appropriate, treated.[1] There have been criticisms over the slow progress with the Lookback. Ministers decided not to speed up detection as the bottleneck would then transfer to hepatology clinics. A list of Ministerial and Departmental commitments on the Lookback is available if required, some of which could be interpreted in a wider context.

Haemophiliacs.

e. **There is pressure for compensation from the Haemophilia Society for those infected through blood products prior to 1985.** Approximately 3000 haemophiliacs are thought to be infected who are not covered by the HIV Payment scheme. Ministers have recently written to the Haemophilia Society to reiterate that compensation will not be paid since no negligence was involved. Ministers have given commitments to help, including investigating alleged problems of access to Alpha Interferon for these patients. So far the few cases identified have been readily resolved.

Pressures on purchasers - availability of treatment.

f. There is already a public perception as well as a Miniserial commitment, that those infected through NHS treatment should be treated if medically appropriate. However, it is clear that some other patients (probably mainly those who have been infected through drugs misuse)

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[1] Interim Report on the Hepatitis C Look Back Exercise submitted to Ministers on 5th February available on request.

are being denied treatment on grounds of cost which is particularly contentious given the wide range of people at risk (eg: health care workers and people who injected drugs 20 years ago who are only now manifesting signs of liver damage). **Distinguishing between people infected through NHS treatment and through other routes such as drug misuse is contentious.** Ministers would be exposed to criticism if it became clear that the Department/NHS was operating a selective policy on testing and/or treatment dependent on the route of infection (shades of the "deserving" and "undeserving" poor) and that those infected by the NHS were being given priority. Pressure groups would rapidly identify any evidence of a two-tier approach if Ministers fail to follow the "Tackling Drugs Together" commitment (see para. 2 above). A press release issued by the British Liver Trust citing the findings of an informal survey of liver units giving details of difficulties in funding this treatment is at Annex B.

g. There are an increasing number of examples of variations in the availability of treatment between purchasers and hospitals coming to light. In Newcastle, for example, whilst the small number of patients treated at the DGH are treated with Alpha Interferon, it is not available for patients referred to the specialist liver unit because of the large numbers involved and the consequent cost. So far, our line has been that it is for Health Authorities to decide on priorities based on local needs but we have not used this line to justify a blanket refusal to treat patients with a particular intervention known to be potentially life-saving - at least in a small proportion of cases.

Funding.

h. The question of funding for counselling and testing has also been raised. The cost of Alpha Interferon alone is high (£2-5000 per patient) and the treatment currently under development even more costly. Pressure groups are drawing comparisons between the government's concerted response to AIDS and the current, lower key response to HCV. On research, for example, some £26m is spent annually on research into AIDS whilst we have so far committed £1m for HCV research (plus the cost of the Health Technology Assessment of the treatment currently being commissioned). This contrast is even more stark given that the numbers infected with HCV are likely to be far greater than the numbers who are HIV positive.

Drug companies.

i. The 3 drug companies that manufacture Alpha Interferon have been lobbying Ministers for some time about the non-availability of Alpha Interferon which was licensed for treating HCV in January 1995. Schering-Plough in particular have mounted a campaign to press Ministers to make the treatment more widely available and to remove the blanket ban allegedly applied in some areas.

Media coverage.

j. There have been a number of articles in the national press recently and a recent "World in Action" programme on hepatitis C and drugs misuse. The focus is usually on the potential large numbers infected, the fact that people who are infected may not know it for years and that the government is doing little to address the problem. Many feature people infected through treatment who are likely to win public sympathy as well as highly articulate people in their 30s/40s holding responsible jobs who misused drugs many years ago and are a far cry from the public perception of drugs misusers.

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